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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/621,543 | 07/18/2003 | Minoru Suzuki | 027550-119 | 2474 |

7590 05/08/2009
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| EXAMINER |
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VU, QUYNH-NHU HOANG

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| ART UNIT | PAPER NUMBER |
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3763

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| MAIL DATE | DELIVERY MODE |
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05/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/621,543 | Applicant(s) SUZUKI ET AL. | |
| | Examiner QUYNH-NHU H. VU | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-17, 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 12/2/08 have been entered.

Claims 16-17 and 20 are present for examination.

Claims 1-15, 18-19 are cancelled.

Specification

This disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01 (o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb. 2000)).

Appropriate correction is required.

Claim Objections

Claim 16 is objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore, the Examiner has objected to the claims for the reason set forth above in the objection to the specification. Appropriate correction is required.

112 6th Acknowledgement

With regard to Applicant's "means for selecting a temporary separation mode during therapy to temporarily stop the therapy"; and "means for temporarily separating said delivery means from said dialysis fluid circuit during said temporary separation mode", the "means for displaying a residual staying time after the temporary separation mode is selected" of claim 16, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
- and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines:

a. the "means for selecting a temporary separation mode" as temporary stoppage. Accordingly, the examiner is interpreting the "means for selecting a temporary separation mode" to encompass temporary stoppage or Power turned off or the Stop/Pause button and its equivalents.

b. the "means for temporarily separating said delivery means from said dialysis fluid circuit during said temporary separation mode" as cutting. Therefore, Examiner can be interpreted such as when the power is turned off. There is no more fluid flow or delivery into the dialysis system. For example: disconnection between the tubes can be equivalents to the means-plus- function limitation. At this point, the machine is STOPPED status.

c. the limitation "means for displaying a residual staying time after the temporary separation mode is selected" can be interpreted as the time remaining of procedure.

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Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crnkowich et al. (US 2003/0018395) in view of Castellanos (US 7,232,419).

Crnkowich discloses a peritoneal dialysis apparatus comprising: dialysate control section 108 inherently comprising at least one dialysis fluid container filled with a dialysis fluid, a dialysis fluid circuit containing at least one drained fluid container for recovering the dialysis fluid, fluid delivery means for delivering the dialysis fluid with said dialysis fluid container as a start point or said drained fluid container as an end point, input means for inputting dialysis conditions, and display means 118 for displaying the inputted dialysis conditions, wherein dialysis is performed by delivering the dialysis fluid to a patient by said delivery means and recovering the drained fluid; said apparatus further comprising: a Tx Clock button 236 for selecting a temporary separation mode during therapy to temporarily stop the therapy (Figs. 3A-C, para [0015]); means for temporarily separating said delivery means from said dialysis fluid circuit during said temporary separation mode (Fig. 3C). At this state, some functions of the medical device are suspended, the treatment is paused (para [0023]); and time remaining segment means 254 (Fig. 2) or 302 (Figs. 3A-C) for displaying a residual staying time after the temporary separation mode is selected.

Crnkowich does not mention that an aseptic separating/joining apparatus in the system.

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As noted that, Applicant does not mention specifically about an aseptic separating/joining apparatus. Examiner interprets broadly as containers or connectors or tubes or catheters under sterilize condition for minimizing the potential of contamination during use.

Castellanos discloses an apparatus 10 for maintaining sterile connections during dialysis therapy.

Thus, it would have been obvious to a person of ordinary skill in the art to update older dialysis devices such as show in Crnkowich including the device of Castellanos into the dialysis system for maintaining sterile connections during dialysis therapy,

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crnkowich in view of Castellanos and further in view of Flinchbaugh (US 2002/0139419).

Crnkowich in view of Castellanos discloses the invention substantially as claimed. Crnkowich in view of Castellanos does not disclose that the means for displaying the residual time is comprises a portable terminal.

Flinchbaugh discloses a programmable apparatus can be used in kidney dialysis (see abstract) comprising: a display can include a transceiver for allowing for remote actuation of the device and/or for sending device date to remote locales, such as but not limited to a nurse station, and the like. The transceiver can be either or both wireless...(para [0051]).

Thus, it would have been obvious to a person of ordinary skill in the art to update older dialysis devices such as show in Crnkowich in view of Castellanos with another feature that are commonly available and understood in the art as shown in Flinchbaugh, in order to gain the commonly understood benefits of such adaptation and simplified and enhanced operation, and the nurse/doctor does not to be attending next to the patient all the times but they are able to know the condition of the patients.

Response to Arguments

Applicant's arguments with respect to claims 16-17 and 20 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763